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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,736	08/02/1999	ELISABETH WOLPERT	000500-182	3510

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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09/13/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/319,736	Applicant(s) WOLPERT	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 148-158, 160, 161, 163 and 164 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 148, 149, 151-156 and 163 is/are allowed.
- 6) ☐ Claim(s) 157, 158, 160, 161 and 164 is/are rejected.
- 7) ☐ Claim(s) 150 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 143-147, 159 and 162 have been canceled. Claims 148-158, 160, 161, 163 and 164 are pending and under consideration.

Claim 150 is objected to because of the following informalities: The claim appears to be missing the words "a polynucleotide" after the word "encoding". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 157, 160, 161 and 164 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the following reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 157 is drawn to a composition comprising cells isolated according to the method of claim 148. Claim 160 is drawn to cells isolated according to the method of claim 148, antigens or epitopes expressed by said cells. Claim 161 is drawn to a composition comprising immunological effector cells isolated according to the method of claim 155 and claim 164 is drawn to a composition comprising effector cells isolated by the method of claim 163. It is noted that claims 157 and 160 are dependent upon the cell isolated by the method of claim 148. The products of claims 157, 160, 161 and 164 lack adequate written description, because the specification cannot adequately describe cells which have yet to be isolated. It logically follows that if a product itself is not adequately described, the method of using said product cannot be adequately described.

Art Unit: 1643

Applicant again argues that the claims are product by process claims which meet the limitations of 112, first paragraph. This is unpersuasive because the isolation of the CTL as the final product are not adequately described because the endogenous epitopes associated with impaired cellular peptide processing cannot be controlled or predicted or described by the process. thus the CTL which recognize such epitopes cannot be adequately described and compositions claims reliant on the identity of the CTL

Claim 158 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising administering to a mammal T cells that selectively recognize cells showing TAP deficient processing of peptides for MHC class I presentation, does not reasonably provide enablement for a method of administering effector cells which are not T cells wherein said effector cell selectively recognize cells showing any type of impaired cellular processing of peptides for MHC presentation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the broadly claimed method.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 158 is drawn to a process comprising administering to a mammal immunological effector cells that selectively show impaired cellular peptide processing for MHC presentation. when given the broadest reasonable interpretation the method includes administering effector cells which include T cells and B cells which selectively recognize cells with impaired processing of peptides by MHC class I or Class II wherein the mechanisms of impaired cellular processing can be at any step in the antigen processing and loading onto either beta-microglobulin of the MHC class I pathway or the invariant chain of the MHC class II pathway. The specification teaches only TAP deficient processing of peptides for MHC class I

Art Unit: 1643

presentation and the ability to generate a subset of antigens which are presented by MHC class I in a TAP independent pathway. The art teaches that newly synthesized class II molecules pass through an endocytic compartment in which they contact peptides derived from endocytosed proteins (Moreno et al, Journal of Immunology, 1991, vol. 147, pp. 3306-3313, page 3310-3311, bridging paragraph) and that the processing of different exogenous and endogenous antigen by different APC occurs in different intracellular compartments. Thus it is reasonable to assume that any of the routes of antigen processing can be subject to defects which result in impaired MHC class II antigen presentation. Further, the art recognizes that DM is required for the correct assembly of processed antigen-Class II complexes (abstract of Green et al, Int Rev Immunology, 1996, Vol. 13, pp. 209-219). The art also teaches that the LMP protein is also involved in the processing of class I MHC peptides (abstract of van Endert et al, Diabetes, 1994 Jan, Vol. 43, pp. 110-117) and it would be reasonable to assume that a defect in the presentation of MHCI could be a result in a defect of LMP or another non-TAP protein involved in MHC class I processing or presentation of peptides (abstract of Rowland-Jones, Eur J Immunol, 1993, vol. 23, pp. 1999-2004). The specification teaches only TAP deficient cells and the presentation of TAP-independent peptides by said cells and the recognition of the presented peptides by effector cells which are deficient in TAP. The scope of the claims should be commensurate with the scope of the enablement set forth, therefore the specification does not provide enablement for the broadly claimed method encompassing the administration to a mammal of any effector cell which selectively recognizes cell showing impaired cellular peptide processing by any mechanisms and including both impaired MHC class I presentation and impaired MHC class II presentation. One of skill in the art would be subject to undue experimentation in order to make the cells having the broadly encompassed impairments in cellular peptide processing for MHC presentation and then make the effector cells which would include B cells which would selectively recognize said cells. .

All other rejections and objections as set forth or maintained in a previous Office action are withdrawn in light of applicants arguments.

Art Unit: 1643

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/

Ph.D., Primary Examiner,

Art Unit 1643